NDA 20-236/S-023
NDA 20-692/S-015

GlaxoSmithKline
P.O.Box 13398
Five Moore Drive
Research Triangle Park, North Carolina 27709

Attention: Roger Gaby
Head, Regulatory Affairs

Dear Mr. Gaby:

Please refer to your supplemental new drug applications dated March 22 and 30, 2001, received March 23 and April 2, 2001 (NDA 20-236/S-023 and NDA 20-692/S-015, respectively), under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serevent (salmeterol xinafoate) Inhalation Aerosol and Serevent Diskus (salmeterol xinafoate inhalation powder).

These "Changes Being Effected" supplemental new drug applications provide for addition of "Oropharyngeal irritation" to the "Observed During Clinical Practice: respiratory" subsection of the ADVERSE REACTIONS section of the labeling.

We have completed the review of these supplemental applications and they are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Parinda Jani, Project Manager, at (301) 827-1064.

Sincerely,

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research